Adverse Event Reporting, CTMS, and CDUS Survey Results

		N	%	N	%
Total Number of Responding Institutions		**21**			
Number of Centers with Legacy System(s)		**19**	**90%**		
Total Number of Legacy Systems				**22**	
Type of AE Data Collection (Current System) (N=22)					
AE Grade				20	**91%**
AE Expectedness				13	**59%**
AE Attribution				20	**91%**
AE relatedness to the Protocol				14	**64%**
CTCAE Toxicity				13	**59%**
Protocol Status				19	**86%**
Study Phase				20	**91%**
Risk-Benefit relationship of the research				6	**27%**
Other				5	**23%**
None/No response				1	**5%**
Current System Functionality (N=22)					
Automated AE Grading				4	**18%**
AE Data Collection				12	**55%**
AE Reporting				7	**32%**
Messaging of SAEs				4	**18%**
Routing AEs				3	**14%**
Integrated AE Repository				10	**45%**
Vocabulary Management				4	**18%**
Participant Self-Reporting				3	**14%**
Public Access to AE Information				2	**9%**
Other				3	**14%**
None/No response				5	**23%**
Desired System Functionality (N=22)					
Automated AE Grading		9	**43%**		
AE Data Collection		3	**14%**		
AE Reporting		6	**29%**		
Messaging of SAEs		6	**29%**		
Routing AEs		8	**38%**		
Integrated AE Repository		3	**14%**		
Vocabulary Management		6	**29%**		
Participant Self-Reporting		5	**24%**		
Public Access to AE Information		4	**19%**		
Other		0	**0%**		
None/No response		12	**57%**		
Summarization of Comments					
Need harmonization of AE terms					
Interaction with the caBIG AE system (N=21)					
Full Implementation	**A**	4	**19%**		
Interface with Legacy AE systems	**B**	10	**48%**		
Other	**C**	4	**19%**		
	A & B	2	**10%**		
	B & C	1	**5%**		
Summarization of Comments					
Streamlined and secure reporting of AEs to External Agencies (e.g., NCI, CTEP, FDA)					

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Total Number of Legacy Systems				**22**	
Interface as much as possible the legacy AE systems with caBIG AE system					
Interaction with the caBIG AE system is dependent on the product that is developed					
Legacy AE Reporting systems/databases (N=22)					
One (1) Legacy System		**16**	**76%**		
Vendor System		8			
Homegrown System		8			
More than One (1) Legacy System		**3**	**14%**		
Vendor System		1			
Homegrown System		5			
No Legacy AE System		**2**	**10%**		
Homegrown Legacy AE System - Open Source (N=13)		**13**			
Yes		3	**23%**		
No		4	**31%**		
No Response		6	**46%**		
Homegrown Legacy AE System - Could your system be contributed to the caBIG effort? (N=13)		**13**			
Yes		4	**31%**		
No		3	**23%**		
No Response		6	**46%**		
Comments					
The vendor of the Oncore system and the institutions with the Oncore system are interested and willing to work with caBIG					
Operating System (N=22)					
DOS				1	**5%**
Red Hat Linux				1	**5%**
Solaris				1	**5%**
Sybase				1	**5%**
Unix				2	**9%**
Unix and Windows				2	**9%**
Web-based				1	**5%**
Windows				11	**50%**
No response				2	**9%**
Database (N=22)					
Oracle	**A**			9	**41%**
Advanced Revelation	**B**			1	**5%**
MS Access	**C**			2	**9%**
MS SQL	**D**			3	**14%**
Ingres	**E**			1	**5%**
	A & C			1	**5%**
	A & D			1	**5%**
No response/Unknowr				4	**18%**
Program Language (N=22)					
ASP.net	**A**	A		1	**5%**
Cold Fusion	**B**	B		2	**9%**
FoxPro 8	**C**	C		0	**0%**

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Ingres Tools	**D**	D		0	**0%**
Java	**E**	E		5	**23%**
MS Access	**F**	F		1	**5%**
Oracle Forms and Reports	**G**	G		1	**5%**
Oracle PL/SQL	**H**	H		0	**0%**
Perl C	**I**	I		0	**0%**
Rbasic	**J**	J		1	**5%**
Visual Basic	**K**	K		0	**0%**
XML	**L**	L		1	**5%**
	B & C			1	**5%**
	D, E, & I			1	**5%**
	G & H			2	**9%**
	E & K			1	**5%**
No response/Unknowr				5	**23%**
Type of CTMS and CDUS Data Capture and Reporting Capabilities (N=21)					
CTMS					
DO NOT have any trials that require CTMS reporting	**A**	6	**29%**		
Data entry into ACES locally and then electronic data transfer to the CTMS database	**B**	4	**19%**		
Application to Application data transfer (Legacy Clinical Trials system to CTMS database)	**C**	2	**10%**		
Requires double data entry to complete submission	**D**	0	**0%**		
Other - Paper, fax	**E**	2	**10%**		
	B, C, & D	1	**5%**		
	B & D	2	**10%**		
	B, C, & E	1	**5%**		
No Response		3	**14%**		
CDUS					
DO NOT have any trials that require CDUS reporting	**A**	5	**24%**		
Data entry into CDUS via web-based data entry application	**B**	6	**29%**		
Data entry into CDUS via CTEP-FTP site	**C**	0	**0%**		
Application to Application data transfer (Legacy Clinical Trials system to CDUS via the CTEP-FTP site)	**D**	1	**5%**		
Application to Application data transfer (Legacy clinical trials system to CDUS)	**E**	0	**0%**		
Create a file from the legacy clinical trials system and send to CDUS via FTP	**F**	2	**10%**		
Requires double data entry to complete submission	**G**	0	**0%**		
Other - Paper, fax	**H**	0	**0%**		
	B & C	2	**10%**		

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	B, D, E, & H	1	**5%**		
	B & G	1	**5%**		
	E & F	1	**5%**		
No Response		2	**10%**		

Summarization of Comments
Use of multiple methods to transfer the AE reports
Tedious, labor intensive process with some double data entry.
Takes several FTEs to complete CDUS submission
Want a secure automated data transfer
Issues/Barriers with CTMS and/or CDUS report systems - Summarization of Comments (Refer to the comments section for all the comments)
Unsecure electronic data transfer
Several iterations of data validation after submission and resubmissions before submission is accepted - waiting for list of errors, correcting the errors and re-submitting the report to CDUS
Unclear CDUS expectations of reporting the data
Nonstandard coding of data and abbreviations
Naming of entities is inconsistent - I.e., same drugs will be abbreviated differently in different studies and
Fixed file lengths of submission fields - many of the file lengths are too short
Theradex - Vague data export specifications and vague or no table specifications
CTMS system automatically defaults to the description rather than the CTC/CTCAE term - this generates potentially unnecessary clarification of data already entered
Clarifications of data are not always sent in a timely manner. Extra time is then spent on clarifying previous submitted data making it difficult to stay current with present data submissions.
Would be beneficial and efficient to have an in-house application to run the CDUS reports and fix the errors before sending to CDUS.
Note: There are still institutions that have not responded to the survey.
Note: Of the 21 Institutions that have responded so far, there are several that have not yet completed the abbreviated v 3.0 survey.
Note: There are some previous surveys that are missing data and require follow up.